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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,843	09/22/2003	Michael Johnson	2098/US	4980

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DENVER, CO 80202-5647

EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,843

Applicant(s)

JOHNSON ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-11,13-20 and 49-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,6-10 and 15-20 is/are allowed.
- 6) ☒ Claim(s) 11,13,14 and 49-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/14/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Entry of Amendment

Applicant's amendment filed on July 14, 2006 is acknowledged. Claims 25-30, 34-30 and 45-48 have been canceled and claims 21-24, 31-33 and 40-44 have been withdrawn by the applicant, thus claims 1, 6-11, 13-20 and 49-55 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action mailed on February 14, 2006. Rejections under 35 U.S.C. 102 with the Hauser et al. reference are maintained for claims 11, 13 and 14 and new grounds of rejection are also presented below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Is the electrically conductive element recited the first, second or both. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,052,407).

As to claim 11 Hauser et al disclose a lead system for eliciting an electrical response from tissue, comprising;

- a lead body (10) solid in lateral cross-section (Figures 1 and 2);

- a lead tip (16) operably connected to the lead body;

- a first electrically conductive element integrally formed with the lead body (12);

- a first energy delivery element (the lead wire # 18 that is connected to a pulse generator or power source) operably connected to the first electrically conductive element;

- a second electrically conductive element integrally formed with the lead body (not shown but similar to lead # 18); and

- a first electrical sensing element (a separate conductive surface - not shown - which the examiner assumes is integrally formed with the lead body similar to # 12, see col. 7, lines 43-47) operably connected to the second electrically conductive element (col. 3, line 46-col. 5, line 14 and col. 7, lines 31-64).

Further to claim 13, Hauser et al. disclose a stylette (22) and a lumen for the stylette (Figure 16 and col. 4, lines 32-55 and col. 7, lines 31-64).

Further to claim 14, Hauser et al. disclose the electrode (10) is connected to a pulse generator or power source (23 and col. 5, lines 1-4) and that diagnostic apparatus

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(e.g., ECG equipment) can be connected to the second electrically conductive element (col. 7, lines 43-47).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers et al. (5,366,443). Eggers et al. disclose a lead or catheter comprising:

a lead body (44) comprising at least one polymeric layer (inherent or typical of the material used in the medical arts for the external sheath of a catheter or lead);

a lead tip (14) operably connected to the lead body;

a first electrically conductive element (one of the wires # 52) integrally formed with the at least one polymeric layer;

a first energy delivery element (electrode # 18) operably connected to the first one electrically conductive element;

a second electrically conductive element (wires 50) integrally formed with the catheter body; and

a first electrical sensing element (thermocouple 48) operably connected to the second electrically conductive element (50: see col. 4, line 31-col. 5, line 39, col. 7, line 18-col. 8, line 29 and col. 11, lines 34-47).

Note that in relation to claim 52 the examiner has assumed that a multiplicity of wires is generally or typically optionally formed as a trace.

Further to claims 53-55, the electrodes (18) are mechanically and thermally coupled to lead wires (52) and the thermocouple wires (48) are electrically insulated from each other by an insulating material (54 e.g., epoxy). This integrally formed bundle is equivalent to co-extrusion because the final product is the claimed invention regardless of its method of manufacture (Product by Process claim, MPEP 2113).

Allowable Subject Matter

Claims 1, 6-10 and 15-20 are allowed.

Claim 50 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Griffin et al. (US 2004/0024397) disclose an ablation catheter with the electrode conductor wires co-extruded with the catheter, but lacks a temperature sensor/thermocouple; Steen et al. (6,213,995) disclose a braided catheter with mechanical and electrical wires formed integrally; and Winker (5,417,208) discloses an electrode carrying catheter with integrally formed wires, but also lacks a temperature sensor(s).

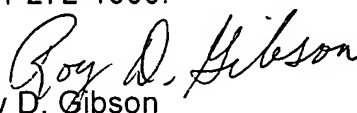
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Note: for typical materials for catheter construction see Berg et al. (6,185,449).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Roy D. Gibson
Primary Examiner
Art Unit 3739

October 2, 2006